Diagnostic Automation / Cortez Diagnostics, Inc.
IMMUNO DIAGNOSTICS

CE

OneStep Scrub Typhus IgG Serum /WB/Plasma RapiDip™ InstaTest

REF **146117-25-25**

A rapid test for the qualitative detection of IgGantibodies to Scrub Typhus antigens in serum, plasma, or whole blood

For research use only. Not for use in diagnostic procedures.

IVD See external Label 20-30°C 25 Tests

Specificity	**100 %**
Sensitivity	**100 %**

INTENDED USE

The Cortez Scrub Typhus IgG Rapid Test RapiDip™ InstaTest is a rapid immunochromatographic immunoassay for the qualitative detection of IgG antibodies to members of *O. tsutsugamushi* (OT) species in human serum, plasma or blood. The intended use is to aid in the presumptive diagnosis of OT infection (scrub typhus).It is for research use only. Not for use in diagnostic procedures.
It is not intended for use by blood donor centers or blood component manufacturers.

SUMMARY AND EXPLANATION

Scrub Typhus (ST) is an infectious disease that is caused by *Orientia tsutsugamushi* (formerly *Rickettsia*), a tiny parasite about the size of bacteria that belongs to the family Rickettsiaceae (1). A bite from the larval trombiculid mite, a parasite of rodents, will transmit the disease. An ulcer of the skin is characteristic of a bite from a trombiculid mite, followed by symptoms including fever, a spotted rash on the torso, and swelling of the lymph glands. After the onset of symptoms, the IgM antibody titers increased gradually over 2–3 weeks, peaked at about 4 weeks, and started to decrease rapidly between 4 and 5 weeks. Over the first 2 weeks, IgG antibody titers increases sharply, peaked at about 4 weeks and decreased rather gradually thereafter (1).
Scrub typhus generally occurs after exposure to areas with secondary (scrub) vegetation, which is where its name is derived from. However, the disease can also be prevalent in sandy, mountainous, and tropical areas. Scrub Typhus is a worldwide illness, but particular to South East Asia and the Western Pacific. It accounts for approximately 20% of fever in some regions in South East Asia, where it is endemic. Illness lasts for a period of 10 to 12 days after the initial bite. With therapy, the fever will break within 36 hours, but if left untreated, complications or death may occur.

TEST PRINCIPLE

The Cortez Scrub Typhus IgG Rapid Test RapiDip™ InstaTest rapid system is a qualitative, membrane-based immunoassay for the detection of IgG. The membrane is pre-coated with a mixture novel recombinants (representing several geographical isolate; 2, 3) on the test line region and appropriate control antigen on the control line region. During testing, the sample reacts with the dye conjugate (anti-human IgG colloidal gold conjugate) which has been pre-coated in the test device. The mixture then migrates upward on the membrane chromatographically by capillary action to react with ST derived recombinant antigens on the membrane and generates a red line. Presence of this red line indicates a positive result, while its absence indicates a negative result. Regardless of the presence of antibody to scrub typhus antigens, as the mixture continues to migrate across the membrane to the immobilized control region, a red line at the control line region will always appear. The presence of this red line serves as verification for sufficient sample volume and proper flow and as a control for the reagents.

SPECIMEN COLLECTION AND PREPARATION

1. The Cortez Scrub Typhus IgG Rapid Test RapiDip™ InstaTest can be performed using serum, plasma or whole blood.
2. Testing should be performed immediately after the specimens have been collected. Do not leave the specimens at room temperature for prolonged periods. The plasma or serum may be stored at 2-8°C for up to 3 days. For long term storage, specimens should be kept below -20°C.
3. Bring specimens to room temperature prior to testing. Frozen specimens must be completely thawed and mixed well prior to testing. Specimens should not be frozen and thawed repeatedly.
4. If specimens are to be shipped, they should be packed in compliance with federal regulations for transportation of etiologic agents.
5.

MATERIALS AND COMPONENTS

Cortez Scrub Typhus IgG Rapid Test strip's membrane is pre-coated with a mixture of ST derived recombinant antigens on the test line region and Protein A binding, or anti-human IgG (for IgG detection) reagents on the control line region.
The Kit contains the following:
1. Twenty-five (25) individually pouched Test Strips or twenty-five (25) test strips in a vial with desiccant on the vial cap.
2. One (1) vial of Chase Buffer solution.

ASSAY PROCEDURE

1. Allow the samples to reach room temperature prior to testing.
2. Remove the Cortez *Scrub Typhus* IgG test from the foil pouch or vial.
3. Add 10µL of sera or whole blood to the test strip in the area beneath the arrow (sample pad area). For addition of the sera, the strip may be placed horizontally on a flat surface or vertically in a microtiter well or test tube.
4. If the test strip is placed horizontally on a flat

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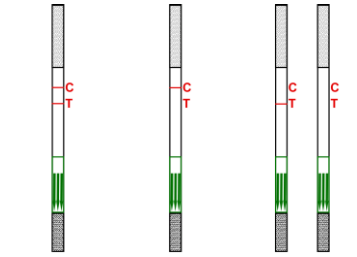
surface, add 3 drops (90-120 □l) of the appropriate Chase Buffer solution provided with the test kits into a test tube or plastic well (with a minimum capacity of 200□l); then place the strip, facing downward (as indicated by arrows on the strip), into the well. Make sure only the open portion of the sample pad is touching the chase buffer.
5. If the strip is placed vertically in the well, then add 3 drops (90-120 □l) of the Chase Buffer solution directly into the well.
6. Read the results in 15 minutes.
7. To ensure the detection of all samples, including those yielding a weak signal in the test region, it is imperative that the testing period be complete and that the background on the strip cleared prior to reading the result. Results interpreted after 15 minutes can be inaccurate.
Note: Do not test this product with the Chase Buffer solution alone. 10□l of human serum or whole blood must be added first.

RESULTS

A Positive Result
The test is positive when a control line (C) and test line (T) appears in the test area as shown in Figure 1A. A positive result indicates that the Cortez Scrub typhus IgG rapid dipstick detected antibodies to mixture of OT derived recombinant antigens. A faint line is considered a positive result. As a guide for interpretation, the red color in the test region (T) will vary depending on the concentration/affinity of antibodies present.

Figure 1
Schematic representation of Scrub typhus reactivity



A Negative Result
The test is negative when only the control line appears (Figure 1B). A negative result indicates that the Cortez Scrub typhus IgG RapiDip™ InstaTest did not detect antibodies to members of *OT derived recombinant* antigens.
An Invalid Result
1. No lines appear at either the control or test line areas.
2. No control line appears, but a test line is seen (Figure 1C).

LIMITATIONS OF PROCEDURE

- The Cortez Scrub Typhus IgG Rapid Test Device is for *research* use only. Not for use in diagnostic procedures. The test should be used for the detection of antibodies to *O. tsutsugamushi* in specimen.
- The Cortez Scrub typhus IgG Rapid Test will only indicate the presence of antibodies to *O. tsutsugamushi* in the specimen and may not imply active infection.
- Do not use serum samples containing any glycerol or other viscous materials. This will decrease the sensitivity of the assay.
- The Cortez Scrub Typhus assays have not been tested In persons with advanced HIV infection or other immunocompromised diseases that are known to have low or undetectable antibodies.
- Rheumatoid Factor containing (RF) sera may produce false positive results when Cortez Scrub Typhus is used.

PRECAUTIONS

□ For *research* use only. Not for use in diagnostic procedures.
□ All human source materials used in the preparation of controls have tested negative for antibodies to HIV 1&2, Hepatitis C and Hepatitis B surface antigen. However, no test method can ensure 100% efficiency. Therefore, all human controls and antigen should be handled as potentially infectious material. The Center for Disease Control and the National Institute of Health recommend that potentially infectious agents be handled at the Biosafety Level
□ Avoid drinking and/or eating in testing areas.
□ A thorough understanding of this package insert is necessary for successful use of the product. Do not mix various lots of any kit component within an individual assay.
□ Do not use any component beyond the expiration date shown on its label.
□ Avoid exposure of the reagents to excessive heat or direct sunlight during storage and incubation.
□ Wear protective clothing, eye protection and disposable gloves while performing the assay. Wash hands thoroughly afterwards.
□ Use a clean disposable pipette tip for each reagent, Standard, Control or specimen.
□ Cover working area with disposable absorbent paper.
□ Avoid all possible contact with skin and mucous membranes.

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STORAGE

The sealed pouch or vial containing the test strip and the bottle containing the Chase Buffer is designed to be stored at room temperature (20C-28C) for the duration of its shelf life. Exposure to temperatures over 30C can impact the performance of the test and should be minimized (5 days maximum). The strips should not be frozen. The test should be used within 1 hour after removal from the pouch or vial to prevent exposure to humidity.

REFERENCE

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ISO 13485
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